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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

HUNTER, RONALD A

ART UNIT

PAPER NUMBER

4185

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/566,009	Applicant(s) MUHLHOFF ET AL.	
	Examiner RONALD HUNTER	Art Unit 4185	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20-46 is/are pending in the application.
- 4a) Of the above claim(s) 1-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 20-46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 January 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/25/2006 & 9/23/2008</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This office action is in response to application no. 10/566009 filed on 1/25/2006.

Specification

The disclosure is objected to because of the following informalities: *Figures 5-13 details not disclosed*. Appropriate correction is required.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, Figures 5-13 must be labeled, shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering

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of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 28, 29, 41 & 42 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. *High orders of curvature not explained.*

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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7. **Claims 20-28, 31-42 & 45** are rejected under 35 U.S.C. 102(b) as being unpatentable by **Swinger et al. (6,325,792 B1)**.

Regarding claim 20, 21, 33, Swinger's invention discloses focusing the laser pulses at a selected interaction point in the material; wherein the selected interaction point has a diameter in a range of about 1 .mu.m to about 30 .mu.m; positioning the laser pulses within a selected portion of the material; determining a position of the laser pulses within the material; controlling the diameter of the laser pulses; determining the diameter of the laser pulses; controlling the intensity of the laser pulses; determining the intensity of the laser pulses; controllably blocking the laser pulses from the material; directing the laser beam to a selected start position within the cornea; scanning a laser spot through the corneal tissue in a predetermined manner such that the lamellar disc of the tissue to be removed is outlined and freed from the surrounding corneal tissue by ablating scanned tissue along a path scanned; whereby an edge shape of the partial thickness lamellar disc is varied as desired for specific applications by altering the path of the scanning spot as it traverses from within the cornea to finally exit the cornea anteriorly (*column 36, line 53- column 37, line 14*), in order to perform intraocular surgical procedures, the laser beam necessarily must pass through overlying tissue to the desired location without damage to the overlying tissue (*column 16, lines 11-13*), meaning the laser beam must function in spatial directions that are perpendicular in respect to each other or three-dimensional in order to achieve depth and area penetration necessary for surgical success. As such changing the

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speed in any of the spatial directions is encompassed in determining the shape and thickness of the cut.

Regarding claim 22, 23, 36, 37, Swinger's invention discloses the excisions illustrated in **FIG. 7** include a straight channel **603**, a curved channel **605**, a point **607**, a line **609**, and interrupted line **611**, a curve of varying depth **613**, a circular area **615**, a square or parallelepiped area **617**, or a spiral **619**. This invention encompasses any combination of such excisions, wherein an ellipticity of 1.0 is a circle.

Regarding claim 24 & 25, Swinger's invention discloses ablation zone edge **224**, surrounded by a plane of annular shape **226** with width **228** and by directing the surgical laser beam S to make a pair of opposing curved excisions **906** along an axis **908** relatively to the center of the eye, the refractive power of the eye is decreased along the axis. The exact length d and the location of the excision can vary according to the amount of desired correction, in known fashion (*column 21, lines 13-19*).

Regarding 26, Swinger's invention discloses scanning a laser spot through the corneal tissue in a predetermined manner such that the lamellar disc of the tissue to be removed is outlined and freed from the surrounding corneal tissue by ablating scanned tissue along a path scanned; whereby an edge shape of the partial thickness lamellar disc is varied as desired for specific applications by altering the path of the scanning spot as it traverses from within the cornea to finally exit the cornea anteriorly (*column 37, lines 6-14*)

Regarding 27, 28, Swinger's invention discloses the scanning of the spot can be carried out in a number of ways, depending on the design of the laser. For example,

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concentric circles, increasing or decreasing spirals, linear scanning while varying the length of each line to allow a circular pattern, etc. have been used with success. After scanning the area **56**, which is a curved surface whose radius of curvature= $R-T4$, the delivery system may be programmed to ablate one or more additional concentric and adjacent surfaces **60**.

Regarding claim 32, Swinger's invention discloses the lasing medium of the pulsed laser apparatus uses lasing ions such as titanium, chromium or neodymium (for example, $Ti_{0.3}Al_{0.2}O_{0.3}$, $Cr:LiSrAlF_6$, $Nd:YLF$, or similar lasers) (*column 36, lines 53-56*), the laser unit **100** includes a seed laser **102** and a scanner-amplifier laser **104** (*column 17, lines 16-17*), and the beam intensity controller 112 is coupled to a computer control unit 114, which is suitably programmed to vary the intensity of the output surgical laser beam S as required for a particular surgical procedure (*Fig. 6; column 17, lines 50-53*) and spot **58** is then moved in a scanning motion under computer control, along the line **56**, which in fact represents the area of ablation of diameter **D6** (*Fig. 15C; column 2, lines 12-14*).

Regarding claim 34, Swinger's invention discloses the adjustable optics comprise a telescope arrangement (*view Fig. 6*).

Regarding claim 35, Swinger's invention discloses the scanning unit comprises two tilting mirrors with crossed axes for rotation to affect the focus shift in the two other spatial directions (*view Fig. 6: 122, 126, 116 & 134*).

Regarding claim 38 & 39, Swinger's invention discloses ablation zone edge **224**, surrounded by a plate of annular shape **226** with width **228** and by directing the

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surgical laser beam **S** to make a pair of opposing curved excisions **906** along an axis **908** relatively to the center of the eye, the refractive power of the eye is decreased along the axis. The exact length **d** and the location of the excision can vary according to the amount of desired correction, in known fashion (*column 21, lines 13-19*), the beam intensity controller **112** is coupled to a computer control unit **114**, which is suitably programmed to vary the intensity of the output surgical laser beam **S** as required for a particular surgical procedure (*Fig. 6; column 17, lines 50-53*) and spot 58 is then moved in a scanning motion under computer control, along the line **56**, which in fact represents the area of ablation of diameter **D6** (*Fig. 15C; column 25, lines 12-14*).

Regarding 40, Swinger's invention discloses scanning a laser spot through the corneal tissue in a predetermined manner such that the lamellar disc of the tissue to be removed is outlined and freed from the surrounding corneal tissue by ablating scanned tissue along a path scanned; whereby an edge shape of the partial thickness lamellar disc is varied as desired for specific applications by altering the path of the scanning spot as it traverses from within the cornea to finally exit the cornea anteriorly (*column 37, lines 6-14*), the beam intensity controller **112** is coupled to a computer control unit **114**, which is suitably programmed to vary the intensity of the output surgical laser beam **S** as required for a particular surgical procedure (*Fig. 6; column 17, lines 50-53*) and spot 58 is then moved in a scanning motion under computer control, along the line **56**, which in fact represents the area of ablation of diameter **D6** (*Fig. 15C; column 25, lines 12-14*).

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Regarding 41 & 42, Swinger's invention discloses the scanning of the spot can be carried out in a number of ways, depending on the design of the laser. For example, concentric circles, increasing or decreasing spirals, linear scanning while varying the length of each line to allow a circular pattern, etc. have been used with success. After scanning the area **56**, which is a curved surface whose radius of curvature= $R-T4$, the delivery system may be programmed to ablate one or more additional concentric and adjacent surfaces **60**, the beam intensity controller **112** is coupled to a computer control unit **114**, which is suitably programmed to vary the intensity of the output surgical laser beam **S** as required for a particular surgical procedure (*Fig. 6; column 17, lines 50-53*) and spot 58 is then moved in a scanning motion under computer control, along the line **56**, which in fact represents the area of ablation of diameter **D6** (*Fig. 15C; column 25, lines 12-14*).

Regarding claim 45, Swinger's invention discloses the excisions illustrated in **FIG. 7** include a straight channel **603**, a curved channel **605**, a point **607**, a line **609**, and interrupted line **611**, a curve of varying depth **613**, a circular area **615**, a square or parallelepiped area **617**, or a spiral **619**. This invention encompasses any combination of such excisions, wherein an ellipticity of 1.0 is a circle, the beam intensity controller **112** is coupled to a computer control unit **114**, which is suitably programmed to vary the intensity of the output surgical laser beam **S** as required for a particular surgical procedure (*Fig. 6; column 17, lines 50-53*) and spot 58 is then moved in a scanning motion under computer control, along the line **56**, which in fact represents the area of ablation of diameter **D6** (*Fig. 15C; column 25, lines 12-14*).

Claim Rejections – 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. **Claims 29, 30, 31, 43, 44 & 46** are rejected under 35 U.S.C. 103(a) as being obvious over **Swinger et al. (US 6,325,792 B1)** in view of **Gerlach et al. (US 6,608,674 B2)**.

Regarding 29 & 43, Swinger's invention discloses a concave applanator plate **111** applied to an eye (*Fig. 14B; column 23, lines 63 & 64*), the beam intensity controller **112** is coupled to a computer control unit **114**, which is suitably programmed to vary the intensity of the output surgical laser beam **S** as required for a particular surgical procedure (*Fig. 6; column 17, lines 50-53*) and spot 58 is then moved in a scanning motion under computer control, along the line **56**, which in fact represents the area of ablation of diameter **D6** (*Fig. 15C; column 25, lines 12-14*), but fails to teach a contact glass.

However, Gerlach teaches a plane-parallel plate 1 made of a material, for example plastic, glass or crystal, which has a refractive index n , is optically transparent of the used wavelength (*column 3, lines 15-19*).

10. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Swinger's invention with a plane-parallel plate **1** made of

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a material, for example plastic, glass or crystal, which has a refractive index n , is optically transparent of the used wavelength of Gerlach.

Doing so would improve laser emission accuracy and efficiency.

Regarding 30, 44 & 46, Swinger's invention discloses this configuration provides positive feed-back of the beam position emanating from the laser unit **100**. If the beam locator sensor **128** detects an out-of-position beam, the computer control unit **114** can take appropriate action, including activation of the safety shutter **120** (*column 19, lines 24-29*), the beam intensity controller **112** is coupled to a computer control unit **114**, which is suitably programmed to vary the intensity of the output surgical laser beam **S** as required for a particular surgical procedure (*Fig. 6; column 17, lines 50-53*) and spot **58** is then moved in a scanning motion under computer control, along the line **56**, which in fact represents the area of ablation of diameter **D6** (*Fig. 15C; column 25, lines 12-14*).

But fails to teach deactivating the laser radiation with respect to generating optical breakthroughs when the contour line extends outside a desired region of the material in which the cut is to be produced.

11. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Swinger's invention by deactivating the laser, wherein deactivation of the laser is considered an appropriate and commonly known response action.

Doing so would prevent damage to peripheral tissue during ophthalmic surgery.

Regarding claim 31, Swinger's invention discloses the excisions illustrated in **FIG. 7** include a straight channel **603**, a curved channel **605**, a point **607**, a line **609**,

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and interrupted line **611**, a curve of varying depth **613**, a circular area **615**, a square or parallelepiped area **617**, or a spiral **619**. This invention encompasses any combination of such excisions, wherein an ellipticity of 1.0 is a circle.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The following references are cited for disclosing related limitations of the applicant's claimed and disclosed invention: **Bille et al. (US 4,901,718 A)**, **Juhasz et al. (US 2003/0014042 A1)**, **Shimmick et al. (US 6,497,701 B2)**, **Juhasz (US 6,110,166 A)**, and **Lai (US 5,984,916 A)**.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RONALD HUNTER whose telephone number is (571)270-7133. The examiner can normally be reached on Monday - Friday, 9:00am - 5:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terrell McKinnon can be reached on (571) 272-4797. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

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For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/RONALD HUNTER/
Examiner, Art Unit 4185

/Terrell L Mckinnon/
Supervisory Patent Examiner, Art Unit 4185